

**CLARITIN- loratadine tablet, chewable**  
**Bayer HealthCare LLC.**

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**Children Claritin® Chewables Perrigo**

**Active ingredient (in each tablet)**

Loratadine 5 mg

**Purpose**

Antihistamine

**Uses**

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

**Warnings**

**Do not use** if you have ever had an allergic reaction to this product or any of its ingredients.

**Ask a doctor before use if you have** liver or kidney disease. Your doctor should determine if you need a different dose.

**When using this product** do not take more than directed. Taking more than directed may cause drowsiness.

**Stop use and ask a doctor if** an allergic reaction to this product occurs. Seek medical help right away.

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

adults and children 6 years and over	chew 2 tablets daily; not more than 2 tablets in 24 hours
children 2 to under 6 years of age	chew 1 tablet daily; not more than 1 tablet in 24 hours

children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

### **Other information**

- phenylketonurics: contains phenylalanine 1.4 mg per tablet
- safety sealed: do not use if the individual blister unit imprinted with Children's Claritin® is open or torn
- store between 20° to 25°C (68° to 77°F)

### **Inactive ingredients**

artificial grape flavor, aspartame, colloidal silicon dioxide, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

### **Questions or comments?**

**1-800-CLARITIN (1-800-252-7484) or [www.claritin.com](http://www.claritin.com)**

Dist by: Bayer HealthCare LLC, Whippany, NJ 07981

Product of Ireland

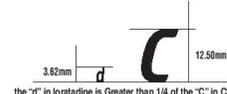
### **PRINCIPAL DISPLAY PANEL**

SIZE: 3.00 x 1.50 x 3.875  
 MATERIAL: 0.014 SBS  
 PRINTED SIDE UP

# 40 CT GRAPE CHEWABLE LORATADINE



**CODE AREA PANEL:**  
 Areas MUST meet background color across entire area (background color must be uniform).  
 Must use a color, preferably a color, over from the job. (White is not acceptable).  
 No text or graphics patterns in code area.  
 Print resolution must be 1200 dpi. Minimum line 1/16" (0.0625") thick.  
 \* Minimum line width 0.0125" (0.0003125")  
 \* Minimum dot size 0.0125" (0.0003125")  
 \* Minimum dot diameter 0.0125" (0.0003125")



the "C" in loratadine is Greater than 1/4 of the "C" in Claritin

## ARTWORK



The Bayer Cross is Less than the "C" in Claritin  
 Current Size: 7mm  
 Current "C" Size: 12.50mm  
 Cross Meets Ratio Requirements of 7mm (.2755") or larger  
 1/4th of Cross required Clear Space (7mm) = 1.75mm  
 1/6th of PDP Shortest Side (76.2mm) = 12.7mm

	18211 NE 68th Street, #120 Redmond, WA 98032 1-800-891-5464	<b>Client:</b> Bayer HealthCare/USA Consumer Healthcare <b>Project type:</b> Production Art
Job #: 402383846	Version: r2	<b>Brand:</b> Claritin
Date: 14JUN2021	Printer: WestPac Allegan	<b>Bayer #/S/NL/Usage:</b> CLARITIN CHILDREN Tablet 40 Piece (PCE) Claritin PCD001676B
Printer Location: MI, US		<b>Item#:</b> C00011389 <b>Dic:</b> BY2894
		<b>EPC (EAN/UPC):</b> 041100575685 <b>UPC Specs:</b> M: 100% H: 18.576 mm
		<b>C128/2x15/20Matrix/Pharma:</b> 34M49B/C1 <b>Software:</b> Illustrator 2020
		<b>File Name:</b> C00011389_CLARITIN_Children_Grape_Tablet_40ct_Carton_r2

Printing Inks	
1 Cyan	5 PMS 287
2 Magenta	6 PMS 3005
3 Yellow	Varnish
4 PMS 186	

Non-Printing		
<input type="checkbox"/> Dieline		
Method of Printing		
<input type="checkbox"/> cornbo		
<input type="checkbox"/> flexo		
<input checked="" type="checkbox"/> offset		
<input type="checkbox"/> screen		
<input type="checkbox"/> pressure		
<input type="checkbox"/> hot stamp		
<input type="checkbox"/> digital		
<input type="checkbox"/> dry offset		

DRUG FACTS INFO (Approved 05/2010)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	5 pt.	5 pt.
Drug Facts Content	8 pt.	8 pt.
Heading*	8 pt bold italic	8 pt.
Subheadings	10 pt.	8 pt.
Body Text	10 pt.	8 pt.
Buttons	8 pt.	3.5 pt.
Caption	10 pt.	10 pt.
Headings	10 pt bold	10 pt.
Box and Barlines	10 pt solid	10 pt.
Character Per Inch	No more than 30	420

\* Headings are not to be used. Do not use the Bayer logo. Do not use the Bayer logo in the background. Do not use the Bayer logo in the background. Do not use the Bayer logo in the background.

# CLARITIN

loratadine tablet, chewable

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11523-0104
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)	LORATADINE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
ASPARTAME (UNII: Z0H242BBR1)	

## Product Characteristics

<b>Color</b>	purple (Light purple tablet with slightly mottled appearance)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	C
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-0104-1	1 in 1 CARTON	02/08/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11523-0104-2	2 in 1 CARTON	02/08/2023	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11523-0104-3	3 in 1 CARTON	02/08/2023	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

4	NDC:11523-0104-4	4 in 1 CARTON	02/08/2023	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:11523-0104-5	6 in 1 CARTON	02/08/2023	
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:11523-0104-6	8 in 1 CARTON	02/05/2023	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210033	02/05/2023	

**Labeler** - Bayer HealthCare LLC. (112117283)

Revised: 12/2025

Bayer HealthCare LLC.